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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,028	02/11/2004	Michael P. Cooke	P1099US10	2201

29490 7590 05/07/2007  
GENOMICS INSTITUTE OF THE  
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EXAMINER
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QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

NOTIFICATION DATE	DELIVERY MODE
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05/07/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org

# Office Action Summary

Application No.

10/777,028

Applicant(s)

COOKE, MICHAEL P.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 19-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 0405.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

**DETAILED ACTION**

Claims 1-30 are pending in the application.

***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 2/9/07 is acknowledged. The traversal is on the ground(s) that there is no legal authority to impose a rejection on a single claim, even if the claim represents multiple independently patentable inventions according to 35 U.S.C.121 and a number of case laws. This is not found persuasive because the invention of Groups I-IV are patentably distinct from each other for reasons set forth of the record mailed on 8/9/06. Moreover, the method of using different gene of different gene constitutes different invention because each gene has its own function and is not obvious variant of each other. A search of all inventions within a single application would not be co-extensive and would be burdensome. MPEP 803 [R3] set forth the guidelines for restriction which includes two criteria: (A) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(j)); and (B) There would be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 808, and § 808.02). This is regardless whether the multiple invention being within one claim or multiple claims. The office action mailed on 8/9/06 has established that the inventions of Groups I-IV and the methods drawn to different genes are distinct and it would have been a burden to search all of them in a single application. As such, for reasons discussed in the previous office action and above, the requirement is still deemed proper and thus made final.

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Accordingly, claims 8-14, 19-30 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-7, 15-18 are currently under examination.

***Claim Objections***

Claims 1-8 and 15-18 are objected to for containing non-elected subject matter. Claims 1 and 15 recites genes that are not Applicant's election. Amending the claims such that they are only directed to elected inventions is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen and Zhang (2001, Experimental Hematology, Vol.29, pages 971-980).

Chen and Zhang discloses introduction of GATA-3 gene by a retroviral vector into primary murine hematopoietic stem cells, wherein the expression of GATA-3 results in the cessation of cell expansion followed by selective induction of megakaryotcytic and erythroid differentiation and inhibition of myeloid and lymphoid differentiation (see abstract and page 975, 2<sup>nd</sup> col., 2<sup>nd</sup> paragraph). Therefore, Chen and Zhang discloses the instantly claimed invention.

Claims 1, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Qiang et al (2000, Science, Vol.290, issue 5489, page 134).

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Qiang et al. disclose that introduction of GATA-3 expression vector into 3T3-F442A preadipocytes results in the inhibition of adipocyte differentiation (see 2<sup>nd</sup> page, 3<sup>rd</sup> paragraph). Therefore, Qiang et al. discloses the instantly claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

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In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The instant claims are drawn to a method of inhibiting differentiation in mammalian stem cells by introducing a vector comprising GATA-3 polynucleotide, wherein the expression of GATA-3 inhibits the stem cell differentiation. The claimed invention encompasses the inhibition of any type of stem cells regardless of their origin and species. The instant specification only discloses that GATA3 are expressed in higher quantity in hematopoietic stem cells in human and mouse HSC. At the time of filing, the anti-differentiation of GATA-3 is only known in pre-adipocytes and HSC. Since stem cell of different origins are regulated by different factors for its proliferation and differentiation, whether GATA3 is able to inhibit differentiation in all types of stem cell in all species of mammal is unpredictable. Since the specification does not describe the claimed invention by a representative number of species by their complete structure, nor other identifying characteristics such as the mechanism of GATA3 for inhibiting differentiation in HSC, the written description requirement is not satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 18 recites the limitation "the subject" in 1. There is insufficient antecedent basis for this limitation in the claim. Claim 15 does not recite any subject.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CELINE QIAN, PH.D.  
PRIMARY EXAMINER



Celine X Qian Ph.D.  
Examiner  
Art Unit 1636